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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,475	01/22/2002	Alexander Gaiger	210121.494C2	3551

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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/057,475	GAIGER ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 7-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 27-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/11/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The Amendments and Remarks filed 8/20/07 in response to the Office Action of 2/20/07 are acknowledged and have been entered.

Claims 27-34 have been added by Applicant.

Claims 1-34 are pending.

Claims 1-5 and 7-26 have been withdrawn.

Claim 6 has been amended by Applicant.

Claims 6 and 27-34 are currently under examination.

The following Office Action contains NEW GROUNDS of rejections necessitated by Amendments.

Rejections Withdrawn

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, is withdrawn in view of amendments.

The rejection of claim 6 under 35 U.S.C. 112 first paragraph, for failing to comply with the written description requirement, is withdrawn in view of amendments. However, it is noted that a new written description rejection necessitated by amendments is set-forth below.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 remains rejected and newly added claims 27-34 are rejected under 35 U.S.C. 112 first paragraph, for failing to comply with the enablement requirement, for the reasons stated in the Office Action of 2/20/07 and for the reasons set-forth below.

While being enabling for a method for detecting the presence of lymphoma in a patient comprising detecting levels of polypeptides comprising the sequence set-forth in SEQ ID NO:9611 in lymphoid samples from said patient and comparing said levels to the levels of polypeptides comprising the sequence set-forth in SEQ ID NO:9611 in lymphoid samples from a subject that does not have lymphoma, wherein higher levels of polypeptides comprising the sequence set-forth in SEQ ID NO:9611 in lymphoid samples from said patient, as compared to levels of polypeptides comprising the sequence set-forth in SEQ ID NO:9611 in lymphoid samples from a subject that does not have lymphoma, indicates that said patient *has* lymphoma, the specification does not reasonably provide enablement for a method for detecting the presence of lymphoma in a patient comprising detecting levels of polypeptides comprising the sequence set-forth in SEQ ID NO:9611 in lymphoid samples from said patient and comparing said levels to the levels of polypeptides comprising the sequence set-forth in SEQ ID NO:9611 in lymphoid samples from a subject that does not have lymphoma,

wherein higher levels of polypeptides comprising the sequence set-forth in SEQ ID NO:9611 in lymphoid samples from said patient, as compared to levels of polypeptides comprising the sequence set-forth in SEQ ID NO:9611 in lymphoid samples from a subject that does not have lymphoma is "indicative of" the presence of lymphoma in the patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In the Reply of 8/20/07, Applicant amended claim 6 to specify that the biological sample is a lymphoid sample. Further, newly added claims 29 and 32 recite B-cell samples and lymph node samples, respectively. The pending claims further recite binding agents that bind to the polypeptide of SEQ ID NO:9611 as the binding agent. The pending claims no longer recite "predetermined cut-off value" and now specify that the amount of polypeptide in step (c) is compared to the amount of polypeptide of SEQ ID NO:9611 in a control sample from a subject that does not have lymphoma.

The amendments to claim 6 has been carefully considered, but are not deemed persuasive. While the amendments addressed a *vast majority* of the enablement issues, the pending claims remain drawn to methods wherein a result (an amount of polypeptide in step (c) that is greater than the amount of polypeptide in the control sample) is "indicative of" the presence of lymphoma in a patient. As indicated on page 11 of the Office Action of 2/20/07, the term "indicative of", as recited in the pending claims, encompasses *contradictory* methods. The claims do not recite how an amount of polypeptide in step (c) that is greater than the amount of polypeptide in the control

sample is indicative of the presence of lymphoma in a patient. Claims drawn to methods wherein a result (an amount of polypeptide in step (c) that is greater than the amount of polypeptide in the control sample) is "indicative of" the presence of lymphoma in a patient broadly read on methods wherein an amount of polypeptide in step (c) that is greater than the amount of polypeptide in the control sample indicates the patient has lymphoma and methods wherein an amount of polypeptide in step (c) that is greater than the amount of polypeptide in the control sample indicates the patient does not have lymphoma. Amending the claims to recite methods of determining whether a patient has lymphoma .... wherein an amount of polypeptide in step (c) that is greater than the amount of polypeptide in the control sample indicates the patient has lymphoma would obviate this rejection.

New Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 27-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 and dependent claims 27-28 are rejected because claim 6 recites the limitation "the biological sample" (see part "(b)" of claim 6). There is insufficient antecedent basis for this limitation in the claim.

Claim 6 and dependent claims 27-28 are rejected because claim 6 recites the limitation "the sample" (see part "(c)" of claim 6). It is unclear whether "the sample" is the "lymphoid sample" or "the biological sample". There is insufficient antecedent basis for this limitation in the claim.

Claim 29 and dependent claims 30-31 are rejected because claim 29 recites the limitation "the biological sample" (see part "(b)" of claim 29). There is insufficient antecedent basis for this limitation in the claim.

Claim 29 and dependent claims 30-31 are rejected because claim 29 recites the limitation "the sample" (see part "(c)" of claim 29). It is unclear whether "the sample" is the "B-cell sample" or "the biological sample". There is insufficient antecedent basis for this limitation in the claim.

Claim 32 and dependent claims 33-34 are rejected because claim 32 recites the limitation "the biological sample" (see part "(b)" of claim 32). There is insufficient antecedent basis for this limitation in the claim.

Claim 32 and dependent claims 33-34 are rejected because claim 32 recites the limitation "the sample" (see part "(c)" of claim 32). It is unclear whether "the sample" is the "lymph node sample" or "the biological sample". There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 29, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of binding agents that bind to the polypeptide of SEQ ID NO:9611. However, the written description in this case only sets forth antibodies that specifically bind to the polypeptide of SEQ ID NO:9611 (see pages 21-22, in particular). The specification does not disclose, and the art does not teach, the genus of binding agents that bind to the polypeptide of SEQ ID NO:9611 as broadly encompassed by the claims.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to that genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43

USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Further, In regards to claims requiring use of a product defined by function, without a correlation between structure and function, the claim does little more than define the product by function. That is not sufficient to satisfy the written description requirement. See Eli Lilly, 119 at1568 USPQ2d at 1406 ("definition by function...does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is").

The inventions at issue in Lilly were DNA constructs per se, the holdings of that case is also applicable to claims such as those at issue here. Further, disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d, 2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of binding agents that encompass the genus nor does it provide a description of structural features that are common to said binding agents. Since the disclosure fails to

describe common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of antibodies that specifically bind to the polypeptide of SEQ ID NO:9611 is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of binding agents, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolation. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only binding agents that bind to the polypeptide of SEQ ID NO:9611 wherein said binding agents are antibodies that specifically bind to the polypeptide of SEQ ID NO:9611, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Summary

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

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